



**PATENT**

Attorney Docket No.: A-63708-6/TAL/NHT

Attorney File No.: 465840-00524

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

BUELOW et al.

Serial No. 10/782,260

Filing Date: February 18, 2004

For: *Methods For Enhancing Graft  
Survival by Modulating Heme  
Oxygenase Activity*

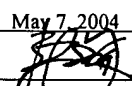
Examiner: Not Yet Assigned

Art Unit: 1632

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Dated: May 7, 2004

Signed:   
Brent Yonehara

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1273 Off. Gaz. Pat. Off. 1, 8/5/2003, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

Further, this application is a continuation of the following related U.S. Application – Serial No. 09/515,582, filed February 29, 2000 (pending). Applicant wishes to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying substitute for form PTO-1449 marked with an asterisk (\*). Since these references were previously disclosed in the above-mentioned application, in accordance with 37 C.F.R. § 1.98(d), no copies of these references are enclosed.

Serial No. 10/782,260  
Filing Date: February 18, 2004

None of the foregoing references are believed to disclose the invention as claimed.


Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.

Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

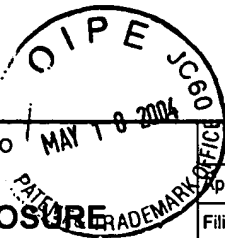
As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. While no fee is believed to be due, if this belief is in error the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 465840-00524 [A-63708-6/TAL/NHT]).

Respectfully submitted,  
DORSEY & WHITNEY LLP

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BY:   
Todd A. Lorenz, Reg. No. 39,754

Attachments : Form PTO/SB/8A, Substitute for form 1449  
25 cited references  
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Substitute for form 1449A/PTO  
(Modified)

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

## **Complete if Known**

Application Number	10/782,260
Filing Date	February 18, 2004
First Named Inventor	BUELOW, Roland
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	33861/US/TAL/NHT ([A-63708-6] 465840-524)

Sheet	1	of	6
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## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1 *	4,829,984	05-16-1989	Gordon	
	A2 *	5,563,132	10-08-1996	Bodaness	
	A3 *	5,756,492	05-26-1998	Buelow et al.	
	A4 *	6,013,641	01-11-2000	Lussow et al.	
	A5 *	6,060,467	05-09-2000	Buelow	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1 *	WO 96/09038 A2	03-28-1996	William Harvey Research Ltd.		
	B2	WO 98/09618 A2/A3	03-12-1998	SangStat Medical Corporation		
	B3	WO 99/23215 A2/A3	05-14-1999	University of Florida		
	B4	WO 00/12118 A2/A3	03-09-2000	President & Fellows of Harvard College		

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	ABRAHAM, N.G., et al., "Retinal pigment epithelial cell-based gene therapy against hemoglobin toxicity," <i>Int. J. Mol. Med.</i> 1:657-663 (1998).	
	C2	ABRAHAM, N.G., et al., "The physiological significance of heme oxygenase," <i>Int. J. Biochem.</i> 20(6):543-558 (1988).	
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	C9 *	BLYDT-HANSEN, T.D., et al., "Heme oxygenase-1 gene transfer protects against ischemia/reperfusion injury in rat renal isograft model," No. 157, <i>Conf. Proc. Transplant 2001</i> , The Joint American Transplant Meeting, Chicago, IL (May 11 - 16, 2001).	

Examiner Signature	Date Considered
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			Filing Date	February 18, 2004	
			First Named Inventor	BUELOW, Roland	
			Art Unit	To be assigned	
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	C10 *	BOASQUEVISQUE, C., et al., "Ex vivo liposome-mediated gene transfer to lung isografts," <i>J. Thorac. Cardiovasc. Surg.</i> 115(1):38-44 (Jan. 1998).		
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	C18 *	CRYSTAL, R.G., "Transfer of genes to humans: early lessons and obstacles to success," <i>Science</i> 270(5235):404-410 (Oct. 1995).		
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	C21 *	DeBRUYNE, L., et al., "Gene transfer of immunomodulatory peptides correlates with heme oxygenase-1 induction and enhanced allograft survival," <i>Transplantation</i> 69(1):120-128 (Jan. 2000).		
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	C25 *	EVANS, C-O, et al., "Cloning and sequencing and expression of cDNA for chick liver heme oxygenase: comparison of avian and mammalian cDNAs and deduced protein," <i>Biochem. J.</i> 273:659-666 (1991).		
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	C27	HANCOCK, W., et al., "Antibody-induced transplant arteriosclerosis is prevented by graft expression of anti-oxidant and anti-apoptotic genes," <i>Nat. Med.</i> 4(12):1392-1396 (Dec. 1998).		
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			Application Number	10782,260	
			Filing Date	February 18, 2004	
			First Named Inventor	BUELOW, Roland	
			Art Unit	To be assigned	
			Examiner Name	To be assigned	
Sheet	3	of	6	Attorney Docket Number	33861/US/TAL/NHT ([A-63708-6] 465840-524)

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	C30 *	ISHIKAWA, K., et al., "Expression of rat heme oxygenase in <i>Escherichia coli</i> as a catalytically active, full length form that binds to bacterial membranes," <i>Eur. J. Biochem.</i> 202:161-165 (1991).	
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	C32 *	JUAN, S.-H., et al., "Adenovirus-mediated heme oxygenase-1 gene transfer inhibits the development of atherosclerosis in apolipoprotein E-deficient mice," <i>Circulation</i> 104:1519-1525 (2001).	
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	C35 *	KUEMMERLE, N.B., et al., "Gene expression after intrarenal injection of plasmid DNA in the rat," <i>Pediatr. Nephrol.</i> 14(2):152-157 (2000).	
	C36 *	LEDLEY, F.D., "Pharmaceutical approach to somatic gene therapy," <i>Pharm. Rev.</i> 13(11):1595-1614 (Nov. 1996).	
	C37 *	LEE, P.J., et al., "Overexpression of heme oxygenase-1 in human pulmonary epithelial cells results in cell growth arrest and increased resistance to hyperoxia," <i>Proc. Natl. Acad. Sci. USA</i> 93(19):10393-10398 (Sep. 1996).	
	C38 *	LEE, R., et al., "Isolated lung liposome-mediated gene transfer produces organ-specific transgenic expression," <i>Ann. Thorac. Surg.</i> 66:903-907 (1998).	
	C39 *	LEVINE, F., et al., "Towards gene therapy of diabetes mellitus," <i>Mol. Med. Today</i> 5:165-171 (Apr. 1999).	
	C40 *	LI, X.K., "Prolonged survival of rat liver allografts transfected with Fas ligand-expressing plasmid," <i>Transplantation</i> 66:1416-1423 (1998).	
	C41	MAGEE, J.C., et al., "Gene transfer of immunosuppressive peptides B2702 and RDP1257 prolongs allograft survival: evidence suggesting a role for heme oxygenase-1," <i>Transplant. Proc.</i> 31(1-2):1194-1194 (Feb. – Mar. 1999).	
	C42	MAINES, M., "Zinc protoporphyrin is a selective inhibitor of heme oxygenase activity in the neonatal rat," <i>Biochim. Biophys. Acta</i> 673:339-350 (1981).	
	C43 *	MARCONI, P., et al., "Replication-defective herpes simplex virus vectors for gene therapy <i>in vivo</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 93(21):11319-11320 (Oct. 1996).	
	C44	MARTASEK, P., et al., "Properties of human kidney heme oxygenase: inhibition by synthetic heme analogues and matalloporphyrins," <i>Biochem. Biophys. Res. Commun.</i> 157(2):480-487 (Dec. 1988).	
	C45 *	McCLAIN, S., et al., "Functional consequences of adenovirus-mediated murine pancreatic gene transfer," <i>Human Gene Ther.</i> 8(6):739-746 (Apr. 1997).	
	C46 *	MELO, L.G., et al., "Gene therapy strategy for long-term myocardial protection using adeno-associated virus mediated delivery of heme oxygenase gene," <i>Circulation</i> 105:602-607 (2002).	
	C47 *	MILLER, N., et al., "Targeted vectors for gene therapy," <i>FASEB J.</i> 9(2):190-199 (Feb. 1995).	

Examiner Signature	Date Considered
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	C48 *	MOFFATT, S.D., et al., "Comparison between tacrolimus and cyclosporine as immunosuppressive agents compatible with tolerance induction by CD4/CD8 blockade," <i>Transplantation</i> 69(8):1724-1726 (Apr. 2000).		
	C49 *	MURUVE, D., et al., "Ex vivo adenovirus-mediated gene therapy leads to long-term expression in pancreatic islet transplants," <i>Transplantation</i> 64(3):542-546 (1997).		
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	C51	NEIL, T.K., et al., "Modulation of corneal heme oxygenase expression by oxidative stress agents," <i>J. Ocular Pharmacol. Therap.</i> 11(3):455-468 (1995).		
	C52 *	NOVOGRODSKY, A., et al., "Immune stimulatory properties of metalloporphyrins," <i>J. Immunol.</i> 143(12):3981-3987 (Dec. 1989).		
	C53 *	OMATA, Y., et al., "Crystallization and preliminary X-ray diffraction studies on the water soluble form of rat heme oxygenase-1 in complex with heme," <i>Acta. Cryst.</i> D54:1017-1019 (1998).		
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	C55 *	OTTERBEIN, L., et al., "Carbon monoxide has anti-inflammatory effects involving the mitogen-activated protein kinase pathway," <i>Nat. Med.</i> 6(4):422-428 (Apr. 2000).		
	C56	PILEGGI, A., et al., "Absence of inducible nitric oxide synthase, and heme oxygenase-1 upregulation result in improved islet graft function," No. 833, <i>Conf. Proc. Transplant 2001</i> , The Joint American Transplant Meeting, Chicago, IL (May 11 - 16, 2001).		
	C57 *	QIN, L., et al., "Multiple vectors effectively achieve gene transfer in a murine cardiac transplant model," <i>Transplantation</i> 59:809-816 (1995).		
	C58 *	QIN, L., et al., "Retrovirus-mediated transfer of viral IL-10 gene prolongs murine cardiac allograft survival," <i>J. Immunol.</i> 156:2316-2323 (1996).		
	C59	RADAELLI, C., "Induction of heme oxygenase-1 improves rat liver transplantation survival by inhibiting apoptosis," No. 410, <i>Conf. Proc. Transplant 2001</i> , The Joint American Transplant Meeting, Chicago, IL (May 11 - 16, 2001).		
	C60 *	RAJU, V., et al., "Coordinated expression and mechanism of induction of HSP32 (heme oxygenase-1) mRNA by hyperthermia in rat organs," <i>Biochim. Biophys. Acta</i> 1217:273-280 (1994).		
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			Application Number	10/782,260	
			Filing Date	February 18, 2004	
			First Named Inventor	BUELOW, Roland	
			Art Unit	To be assigned	
			Examiner Name	To be assigned	
Sheet	5	of	6	Attorney Docket Number	33861/US/TAL/NHT ([A-63708-6] 465840-524)

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	C66 *	SCHULER, W., et al., "SDZ RAD, a new rapamycin derivative: pharmacological properties <i>in vitro</i> and <i>in vivo</i> ," <i>Transplantation</i> 64(1):32-35 (Jul. 1997).		
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	C68 *	SHAKED, A., et al., "Retroviral-mediated gene transfer into rat experimental liver transplant," <i>Transplantation</i> 57:32-34 (1994).		
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	C71 *	SONG, Y.K., et al., "Enhanced gene expression in mouse lung by prolonging the retention time of intravenously injected plasmid DNA," <i>Gene Ther.</i> 5(11):1531-1537 (1998).		
	C72	SQUIERS, E., et al., "Prolongation of porcine islet xenograft survival in mice after therapy with immunosuppressive peptides," <i>Transplantation</i> 66(11):1558-1565 (Dec. 1998).		
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	C75 *	VERMA, I., et al., "Gene therapy – promises, problems and prospects," <i>Nature</i> 389(6648):239-242 (Sep. 1997).		
	C76 *	VORBURGER, S., et al., "Adenoviral Gene Therapy," <i>Oncologist</i> 7(1):46-59 (Feb. 2002).		
	C77 *	WANG, J., et al., "Adenovirus-mediated gene transfer into rat cardiac allografts," <i>Transplantation</i> 61(12):1726-1729 (Jun. 1996).		
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	C83 *	WRINGER, E.J., et al., "Antagonizing leukotriene B4 receptors delays cardiac allograft rejection in mice," <i>Transplantation</i> 67(6):808-815 (Mar. 1999).		
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	C86	ZHU, N., et al., "Systemic gene expression after intravenous DNA delivery into adult mice," <i>Science</i> 261(5118):208-211 (Jul. 1993).	

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